

REMARKS

Claims 1, 6-13, 24 and 49-55 are currently pending in the above-referenced patent application. Claims 1, 6-10, 12-13 and 24 are amended. Claims 49-55 are added. Applicants respectfully submit that no new matter has been added by way of the amendments to the claims. **In the Office Action:** The benefit under 35 U.S.C. § 120 was acknowledged. The Specification was objected to because of informalities. Claims 1, 6-13 and 24 were rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement.

In reply to the acknowledgement of the benefit under 35 U.S.C. § 120, the Applicants respectfully request reconsideration. Applicants respectfully note the Office Action's acknowledgment at page 3, lines 16-19 of the priority claim to International Application PCT/US04/02064. Applicants have amended the first paragraph of the specification to reflect the priority claim in accordance with the Office Action's recommendations. Accordingly, Applicants respectfully request favorable reconsideration of the specification.

In reply to the objection to the specification due to informalities, the Applicants respectfully request reconsideration. Applicants have, without consenting to the propriety of the objections, amended the specification to advance prosecution and render the objections moot. Tables 1 and 2 introduced at page 7, lines 26-27, and shown at pages 20-25 and 29-45 of the Application have been replaced with higher resolution versions. References shown at pages 26-28 and 46-53 of the Application have also been replaced with higher resolution versions. Accordingly,

Applicants respectfully request withdrawal of the objections and favorable reconsideration of the specification.

In reply to the rejection of claims 1, 6-13 and 24 under 35 U.S.C. § 112, first paragraph, the Applicants respectfully request reconsideration. Applicants have, without consenting to the propriety of the rejection, amended the claims to advance prosecution and render the rejections moot. Claims 1, 6-13 and 24 recite "...administering a vaccinia virus in an effective amount at least to diminish the replication at least of CCR5-tropic HIV in a subject."

The Office Action asserts at page 6, lines 16-24 that "[t]he disclosure fails to provide sufficient guidance pertaining to the mechanism of inhibition." As disclosed in some aspects of embodiments at page 5, lines 13-17 of the Application, a vaccinia virus is a preferred poxvirus, and any poxvirus which expresses a gp-120 like or TAT-like polypeptide, or which depends on CCR5 for entry into a cell can be used. (*See also*, e.g., Application page 8, lines 3-19). As described in further aspects of embodiments at page 4, lines 1-21 of the Application, Dryvax® may be utilized. (*See also*, e.g., Application page 5, lines 22-33). As acknowledged by the Office Action at page 6, lines 27-29, "...there was a reduction in viral replication...CCR5-tropic isolate..." (*See e.g.*, Application FIGS. 1A and 1B). Therefore, Applicants respectfully submit that the disclosure provides sufficient guidance pertaining to administering a vaccinia virus in an effective amount at least to diminish the replication at least of CCR5-tropic HIV in a subject.

The Office Action also asserts at page 6, lines 25-26 that "[t]he disclosure fails to provide any suitable working embodiments." As acknowledged by the Office Action at

page 6, lines 27-29, "...there was a reduction in viral replication...CCR5-tropic isolate..."

As disclosed in some aspects of embodiments at page 18, lines 15-30 of the Application, there was a significant reduction in CCR5 viral replication, with two subjects exhibiting a complete lack of CCR5 viral replication. (See e.g., Application FIGS. 1A and 1B). Furthermore, *in vitro* culture assays are reasonably predictive of clinical efficacy in this case. For example, peripheral blood mononuclear cell (PBMC) models are recognized as standard screening tests for determining whether compounds may be useful at least to diminish the replication of HIV, and the working embodiments in the Application provide statistically significant tests illustrating, at least, diminishing the replication of HIV using a poxvirus, for example with and/or without serum. (*In re Brana*, 51 F.3d 1560, 1566, 34 USPQ2d 1436, 1441 (Fed. Cir. 1995) (reversing the PTO decision based on finding that *in vitro* data did not support *in vivo* applications)). Therefore, Applicants respectfully submit that the disclosure provides suitable working embodiments pertaining to administering a vaccinia virus in an effective amount at least to diminish the replication at least of CCR5-tropic HIV in a subject.

Accordingly, Applicants respectfully request withdrawal of the rejections and favorable consideration of claims 1, 6-13 and 24.

Applicants respectfully request favorable consideration of new claims 49-55. Claim 49 depends directly from claim 24. Claims 51-55 depend, directly or indirectly, from claim 50. At least for the reasons presented above, Applicants respectfully submit claims 49-55 fully comply with the enablement requirement under 35 U.S.C. § 112, first paragraph. Accordingly, Applicants respectfully request favorable consideration of claims 49-50.

CONCLUSION

Applicants believe that a full and complete response has been made to the Office Action and respectfully submit that all of the stated objections and grounds for rejection have been overcome or rendered moot. Accordingly, Applicants respectfully submit that all pending claims are allowable and that the application is in condition for allowance.

Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact the Applicants' undersigned representative at the number below to expedite prosecution.

Prompt and favorable consideration of this Reply is respectfully requested.

Respectfully Submitted,

/EGR, Reg. No. 63,604/
Edgar G. Rodriguez
Reg. No. 63,604

Sherr & Vaughn, PLLC
620 Herndon Parkway
Suite 320
Herndon, Virginia 20170
Tel: 571-313-7577
Fax: 703-935-8473